



February 19, 2016

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## ENGROSSED SENATE BILL No. 297

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DIGEST OF SB 297 (Updated February 17, 2016 8:59 pm - DI 77)

**Citations Affected:** IC 12-15; IC 12-23; noncode.

**Synopsis:** Opioid dependence treatment. Requires Medicaid coverage for inpatient detoxification for the treatment of opioid or alcohol dependence. Adds requirements for an opioid treatment program to meet in order to operate in Indiana. Requires the division of mental health and addiction (division) to adopt specified administrative rules concerning opioid treatment by an opioid treatment provider. Requires the office of the secretary and the division to develop a treatment protocol containing best practice guidelines for the treatment of opiate dependent patients to be used by certain office based opioid treatment providers. Requires an opioid treatment program to provide specified information upon request by the division. Urges the legislative council to assign a study committee the topic of patient access to and provider reimbursement for federally approved medication assisted treatment in the Medicaid program.

**Effective:** Upon passage; July 1, 2016.

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**Miller Patricia, Becker, Mrvan,  
Merritt, Stoops, Charbonneau,  
Randolph Lonnie M**

(HOUSE SPONSORS — KIRCHHOFFER, DAVISSON, ZIEMKE, BROWN C)

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January 7, 2016, read first time and referred to Committee on Health & Provider Services.  
January 21, 2016, amended, reported favorably — Do Pass.  
January 25, 2016, read second time, amended, ordered engrossed.  
January 26, 2016, engrossed. Read third time, passed. Yeas 35, nays 14.

HOUSE ACTION

February 9, 2016, read first time and referred to Committee on Public Health.  
February 18, 2016, amended, reported — Do Pass.

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ES 297—LS 6841/DI 104





February 19, 2016

Second Regular Session 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

## ENGROSSED SENATE BILL No. 297

A BILL FOR AN ACT to amend the Indiana Code concerning human services.

*Be it enacted by the General Assembly of the State of Indiana:*

1       SECTION 1. IC 12-15-5-13, AS ADDED BY P.L.209-2015,  
2       SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  
3       JULY 1, 2016]: Sec. 13. (a) The office shall provide coverage for  
4       treatment of opioid or alcohol dependence that includes the following:

5               (1) Counseling services that address the psychological and  
6               behavioral aspects of addiction.

7               (2) When medically indicated, drug treatment involving agents  
8               approved by the federal Food and Drug Administration for the:

9                       (A) treatment of opioid or alcohol dependence; or

10                      (B) prevention of relapse to opioids or alcohol after  
11                      detoxification.

12               **(3) Inpatient detoxification:**

13                      **(A) in accordance with:**

14                               (i) the most current edition of the American Society of  
15                               Addiction Medicine Patient Placement Criteria; or

16                               (ii) other clinical criteria that are determined by the  
17                               office and are evidence based and peer reviewed; and

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- 1                   **(B) when determined by the treatment plan to be medically**  
 2                   **necessary.**  
 3           (b) The office shall:  
 4               (1) develop quality measures to ensure; and  
 5               (2) require a Medicaid managed care organization to report;  
 6 compliance with the coverage required under subsection (a).  
 7           (c) The office may implement quality capitation withholding of  
 8 reimbursement to ensure that a Medicaid managed care organization  
 9 has provided the coverage required under subsection (a).  
 10           (d) The office shall report the clinical use of the medications  
 11 covered under this section to the mental health Medicaid quality  
 12 advisory committee established by IC 12-15-35-51. The mental health  
 13 Medicaid quality advisory committee may make recommendations to  
 14 the office concerning this section.  
 15           SECTION 2. IC 12-23-18-0.5, AS AMENDED BY P.L.1-2009,  
 16 SECTION 108, IS AMENDED TO READ AS FOLLOWS  
 17 [EFFECTIVE JULY 1, 2016]: Sec. 0.5. (a) An opioid treatment  
 18 program shall not operate in Indiana unless **the opioid treatment**  
 19 **program meets the following conditions:**  
 20               (1) ~~the opioid treatment program~~ Is specifically approved and the  
 21 opioid treatment facility is certified by the division. ~~and~~  
 22               (2) ~~the opioid treatment program~~ Is in compliance with state and  
 23 federal law.  
 24               **(3) Provides treatment for opioid addiction using a drug**  
 25 **approved by the federal Food and Drug Administration for**  
 26 **the treatment of opioid addiction, including:**  
 27                   (A) opioid maintenance;  
 28                   (B) detoxification;  
 29                   (C) overdose reversal;  
 30                   (D) relapse prevention; and  
 31                   (E) long acting, nonaddictive medication assisted treatment  
 32 medications.  
 33               **(4) Beginning July 1, 2017, is:**  
 34                   (A) enrolled:  
 35                       (i) as a Medicaid provider under IC 12-15; and  
 36                       (ii) as a healthy Indiana plan provider under  
 37 IC 12-15-44.2; or  
 38                   (B) enrolled as an ordering, prescribing, or referring  
 39 provider in accordance with Section 6401 of the federal  
 40 Patient Protection and Affordable Care Act (P.L. 111-148),  
 41 as amended by the federal Health Care and Education  
 42 Reconciliation Act of 2010 (P.L. 111-152) and maintains a



**memorandum of understanding with a community mental health center for the purpose of ordering, prescribing, or referring treatments covered by Medicaid and the healthy Indiana plan.**

(b) Separate specific approval and certification under this chapter is required for each location at which an opioid treatment program is operated. **If an opioid treatment program moves the opioid treatment program's facility to another location, the opioid treatment program's certification does not apply to the new location and certification for the new location under this chapter is required.**

(c) Each opioid treatment program that is enrolled as an ordering, prescribing, or referring provider shall report to the office on an annual basis the services provided to Indiana Medicaid patients. The report must include the following:

- (1) The number of Medicaid patients seen by the ordering, prescribing, or referring provider.
- (2) The services received by the provider's Medicaid patients, including any drugs prescribed.
- (3) The number of Medicaid patients referred to other providers.
- (4) Any other provider types to which the Medicaid patients were referred.

SECTION 3. IC 12-23-18-5, AS AMENDED BY P.L.7-2015, SECTION 38, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 5. (a) The division shall adopt rules under IC 4-22-2 to establish the following:

(1) Standards for operation of an opioid treatment program in Indiana, including the following requirements:

(A) An opioid treatment program shall obtain prior authorization from the division for any patient receiving more than seven (7) days of opioid **maintenance** treatment medications at one (1) time and the division may approve the authorization only under the following circumstances:

- (i) A physician licensed under IC 25-22.5 has issued an order for the opioid treatment medication.
- (ii) The patient has not tested positive under a drug test for a drug for which the patient does not have a prescription for a period of time set forth by the division.
- (iii) The opioid treatment program has determined that the benefit to the patient in receiving the take home opioid treatment medication outweighs the potential risk of



diversion of the take home opioid treatment medication.

(B) Minimum requirements for a licensed physician's regular:

(i) physical presence in the opioid treatment facility; and

(ii) physical evaluation and progress evaluation of each opioid treatment program patient.

(C) Minimum staffing requirements by licensed and unlicensed personnel.

(D) Clinical standards for the appropriate tapering of a patient on and off of an opioid treatment medication.

(2) A requirement that, not later than February 28 of each year, a current diversion control plan that meets the requirements of 21 CFR Part 290 and 42 CFR Part 8 be submitted for each opioid treatment facility.

(3) Fees to be paid by an opioid treatment program for deposit in the fund for annual certification under this chapter as described in section 3 of this chapter.

The fees established under this subsection must be sufficient to pay the cost of implementing this chapter.

(b) The division shall conduct an annual onsite visit of each opioid treatment program facility to assess compliance with this chapter.

(c) Not later than April 1 of each year, the division shall report to the general assembly in electronic format under ~~IC 5-14-3~~ **IC 5-14-6** the number of prior authorizations that were approved under subsection (a)(1)(A) in the previous year and the time frame for each approval.

SECTION 4. IC 12-23-18-5.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 5.3. Subject to federal law and consistent with standard medical practices in opioid treatment for substance abuse, the division shall adopt rules under IC 4-22-2 concerning opioid treatment by an opioid treatment provider, including the following:**

**(1) A requirement that the opioid treatment provider periodically review with the patient the patient's treatment plan. In the review, the opioid treatment provider shall consider changes to the plan with the goal of requiring the minimal clinically necessary medication dose, including, when appropriate, the goal of opioid abstinence.**

**(2) Treatment protocols containing best practice guidelines for the treatment of opiate dependent patients, including the following:**

**(A) Appropriate clinical use of all drugs approved by the federal Food and Drug Administration for the treatment**



of opioid addiction, including the following when available:

- (i) Opioid maintenance.
- (ii) Detoxification.
- (iii) Overdose reversal.
- (iv) Relapse prevention.
- (v) Long acting, nonaddictive medication assisted treatment medications.

(B) Requirement of initial and periodic behavioral health assessments for each patient.

(C) Appropriate use of providing overdose reversal, relapse prevention, counseling, and ancillary services.

(D) Transitioning off agonist and partial agonist therapies with the goal, when appropriate, of opioid abstinence.

(E) Training and experience requirements for providers who treat and manage opiate dependent patients.

(F) Requirement that a provider who prescribes opioid medication for a patient periodically review INSPECT (as defined in IC 35-48-7-5.2) concerning controlled substance information for the patient.

SECTION 5. IC 12-23-18-7.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 7.5. (a) This section applies to an office based opioid treatment provider who:

- (1) has obtained a waiver from the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and meets the qualifying standards required to treat opioid addicted patients in an office based setting; and
- (2) has a valid federal Drug Enforcement Administration registration number and identification number that specifically authorizes treatment in an office based setting.

(b) The office of the secretary and the division shall develop a treatment protocol containing best practice guidelines for the treatment of opiate dependent patients. The treatment protocol must require the minimal clinically necessary medication dose, including, when appropriate, the goal of opioid abstinence, and including the following:

- (1) Appropriate clinical use of any drug approved by the federal Food and Drug Administration for the treatment of opioid addiction, including the following:
  - (A) Opioid maintenance.
  - (B) Opioid detoxification.
  - (C) Overdose reversal.



**(D) Relapse prevention.**

**(E) Long acting, nonaddictive medication assisted treatment medications.**

**(2) A requirement for initial and periodic behavioral health assessments for each patient.**

**(3) Appropriate use of providing overdose reversal, relapse prevention, counseling, and ancillary services.**

**(4) Transitioning off agonist and partial agonist therapies, when appropriate, with the goal of opioid abstinence.**

**(5) Training and experience requirements for prescribers of drugs described in subdivision (1) in the treatment and management of opiate dependent patients.**

**(6) A requirement that prescribers obtain informed consent from a patient concerning all available opioid treatment options, including each option's potential benefits and risks, before prescribing a drug described in subdivision (1).**

**(c) Before December 31, 2016, the office of the secretary shall recommend the clinical practice guidelines required under subsection (b) to:**

**(1) the Indiana professional licensing agency established under IC 25-1-5;**

**(2) the office of Medicaid policy and planning established under IC 12-8-6.5; and**

**(3) a managed care organization that has contracted with the office of Medicaid policy and planning.**

SECTION 6. IC 12-23-18-8, AS ADDED BY P.L.131-2014, SECTION 5, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 8. (a) As used in this section, "dispense" means to deliver a controlled substance to an ultimate user.

(b) Subject to the federal patient confidentiality requirements under 42 CFR Part 2, when an opioid treatment program dispenses a controlled substance designated by the Indiana board of pharmacy under IC 35-48-2-5 through 35-48-2-10, the opioid treatment program shall provide the following information upon request from the division:

(1) The medications dispensed by the program.

(2) The medication delivery process, which includes whether the medication was in liquid, film, or another form.

(3) The number of doses dispensed of each medication.

(4) The dosage quantities for each medication.

(5) The number of patients receiving take home medications.

(6) The number of days of supply dispensed.

(7) Patient demographic information for each medication,





including gender, age, and time in treatment.

(8) The dispenser's United States Drug Enforcement Agency registration number.

**(9) The average number of patients served by:**

**(A) the opioid treatment program annually; and**

**(B) each employed or contracted prescriber of the opioid treatment program.**

**(10) The annual ratio of employed or contracted prescribers to patients served at each opioid treatment program.**

**(11) The number of patients and the average length of treatment for each medication dispensed by the opioid treatment program.**

**(12) The number of patients completing an opiate treatment program treatment service having transitioned to opioid abstinence, including the use of long acting, nonaddictive medication for relapse prevention.**

**(13) The number of patients demonstrating improvement in functioning, as defined by the division, while in treatment at an opiate treatment program.**

**(14) An annual submission of each opiate treatment program's policy concerning:**

**(A) the use of INSPECT (as defined in IC 35-48-7-5.2);**

**(B) the protocol for addressing patients who are found, using INSPECT data, to have prescriptions for a controlled substance, including benzodiazepines or other opiate medications; and**

**(C) the protocol for addressing patients who have illicit urine drug screens indicating the use of a controlled substance, including benzodiazepines or other opiates, whether prescribed or not.**

**(15) The number of patients denied access to services due to inability to pay, including the demographic information of the patient concerning race.**

(c) An opioid treatment program shall provide the information required under this section to the division in a manner prescribed by the division.

(d) The division shall annually report the information collected under this section to the legislative council in an electronic format under IC 5-14-6 not later than October 1.

**SECTION 7. [EFFECTIVE UPON PASSAGE] (a) As used in this SECTION, "legislative council" refers to the legislative council established by IC 2-5-1.1-1.**



1       (b) As used in this SECTION, "study committee" means either  
2 of the following:

3           (1) A statutory committee established under IC 2-5.

4           (2) An interim study committee.

5       (c) The legislative council is urged to assign to the appropriate  
6 study committee the topic of patient access to and provider  
7 reimbursement for federal Food and Drug Administration  
8 approved medication assisted treatment in the Medicaid program.

9       (d) If the topic described in subsection (c) is assigned to a study  
10 committee, the study committee shall issue a final report on the  
11 topic to the legislative council in an electronic format under  
12 IC 5-14-6 not later than November 1, 2016.

13       (e) This SECTION expires January 1, 2017.

14       SECTION 8. An emergency is declared for this act.



## COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 297, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 2, line 12, delete ", including the development of a" and insert ". "

Page 2, delete lines 13 through 38.

Page 4, delete lines 10 through 32.

Page 6, line 16, delete "Is:" and insert **"Is, before December 31, 2016:"**.

Page 8, line 1, delete ", when appropriate," and insert **"of requiring the minimal clinically necessary medication dose, including, when appropriate, the goal"**.

Page 8, between lines 26 and 27, begin a new paragraph and insert:  
**"SECTION 8. IC 12-23-18-7.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 7.5. The office of the secretary and the division shall develop a treatment protocol containing best practice guidelines for the treatment of opiate dependent patients. The treatment protocol must require the minimal clinically necessary medication dose, including, when appropriate, the goal of opioid abstinence, and including the following:**

**(1) Appropriate clinical use of any drug approved by the federal Food and Drug Administration for the treatment of opioid addiction, including the following:**

**(A) Opioid maintenance.**

**(B) Opioid detoxification.**

**(C) Overdose reversal.**

**(D) Relapse prevention.**

**(E) Long acting, nonaddictive medication assisted treatment medications.**

**(2) A requirement for initial and periodic behavioral health assessments for each patient.**

**(3) Appropriate use of providing overdose reversal, relapse prevention, counseling, and ancillary services.**

**(4) Transitioning off agonist and partial agonist therapies, when appropriate, with the goal of opioid abstinence.**

**(5) Training and experience requirements for prescribers of drugs described in subdivision (1) in the treatment and management of opiate dependent patients.**



**(6) A requirement that prescribers obtain informed consent from a patient concerning all available opioid treatment options, including each option's potential benefits and risks, before prescribing a drug described in subdivision (1)."**

Page 9, line 6, delete ";" and insert "annually;"

Page 9, line 9, after "(10)" insert **"The annual ratio of employed or contracted prescribers to patients service at each opioid treatment program.**

**(11)".**

Page 9, line 12, delete "(11)" and insert "(12)".

Page 9, line 12, delete "successfully transitioned to" and insert **"completing an opiate treatment program treatment service having transitioned to opioid abstinence, including the use of long acting, nonaddictive medication for relapse prevention."**

Page 9, delete lines 13 through 18, begin a new line block indented and insert:

**"(13) The number of patients demonstrating improvement in functioning, as defined by the division, while in treatment at an opiate treatment program.**

**(14) An annual submission of each opiate treatment program's policy concerning:**

**(A) the use of INSPECT (as defined in IC 35-48-7-5.2);**

**(B) the protocol for addressing patients who are found, using INSPECT data, to have prescriptions for a controlled substance, including benzodiazepines or other opiate medications; and**

**(C) the protocol for addressing patients who have illicit urine drug screens indicating the use of a controlled substance, including benzodiazepines or other opiates, whether prescribed or not."**

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 297 as introduced.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 6, Nays 2.



# SENATE MOTION

Madam President: I move that Senate Bill 297 be amended to read as follows:

Page 2, delete lines 13 through 42.

Page 3, delete lines 1 through 25.

Renumber all SECTIONS consecutively.

(Reference is to SB 297 as printed January 22, 2016.)

MILLER PATRICIA

## COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 297, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 1, line 13, after "with" insert ":

(i)".

Page 1, line 15, delete "and" and insert "or".

Page 1, between lines 15 and 16, begin a new line triple block indented and insert:

**"(ii) other clinical criteria that are determined by the office and are evidence based and peer reviewed; and".**

Page 2, delete lines 13 through 42.

Page 3, delete lines 1 through 19.

Page 3, delete lines 38 through 42, begin a new line block indented and insert:

**"(4) Beginning July 1, 2017, is:**

**(A) enrolled:**

**(i) as a Medicaid provider under IC 12-15; and**

**(ii) as a healthy Indiana plan provider under IC 12-15-44.2; or**

**(B) enrolled as an ordering, prescribing, or referring provider in accordance with Section 6401 of the federal Patient Protection and Affordable Care Act (P.L. 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) and maintains a memorandum of understanding with a community mental health center for the purpose of ordering, prescribing, or referring treatments covered by Medicaid and the healthy**



**Indiana plan."**

Page 4, delete lines 1 through 4.

Page 4, between lines 11 and 12, begin a new paragraph and insert:

**"(c) Each opioid treatment program that is enrolled as an ordering, prescribing, or referring provider shall report to the office on an annual basis the services provided to Indiana Medicaid patients. The report must include the following:**

- (1) The number of Medicaid patients seen by the ordering, prescribing, or referring provider.**
- (2) The services received by the provider's Medicaid patients, including any drugs prescribed.**
- (3) The number of Medicaid patients referred to other providers.**
- (4) Any other provider types to which the Medicaid patients were referred."**

Page 6, line 10, after "7.5." insert **"(a) This section applies to an office based opioid treatment provider who:**

- (1) has obtained a waiver from the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and meets the qualifying standards required to treat opioid addicted patients in an office based setting; and**
- (2) has a valid federal Drug Enforcement Administration registration number and identification number that specifically authorizes treatment in an office based setting.**

**(b)".**

Page 6, between lines 37 and 38, begin a new paragraph and insert:

**"(c) Before December 31, 2016, the office of the secretary shall recommend the clinical practice guidelines required under subsection (b) to:**

- (1) the Indiana professional licensing agency established under IC 25-1-5;**
- (2) the office of Medicaid policy and planning established under IC 12-8-6.5; and**
- (3) a managed care organization that has contracted with the office of Medicaid policy and planning."**

Page 7, line 21, delete "service" and insert **"served"**.

Page 7, after line 42, begin a new line block indented and insert:

**"(15) The number of patients denied access to services due to inability to pay, including the demographic information of the patient concerning race."**

Page 8, after line 6, begin a new paragraph and insert:

**"SECTION 8. [EFFECTIVE UPON PASSAGE] (a) As used in this**



**SECTION, "legislative council" refers to the legislative council established by IC 2-5-1.1-1.**

**(b) As used in this SECTION, "study committee" means either of the following:**

- (1) A statutory committee established under IC 2-5.**
- (2) An interim study committee.**

**(c) The legislative council is urged to assign to the appropriate study committee the topic of patient access to and provider reimbursement for federal Food and Drug Administration approved medication assisted treatment in the Medicaid program.**

**(d) If the topic described in subsection (c) is assigned to a study committee, the study committee shall issue a final report on the topic to the legislative council in an electronic format under IC 5-14-6 not later than November 1, 2016.**

**(e) This SECTION expires January 1, 2017.**

**SECTION 9. An emergency is declared for this act."**

**Renumber all SECTIONS consecutively.**

and when so amended that said bill do pass.

(Reference is to SB 297 as reprinted January 26, 2016.)

KIRCHHOFFER

Committee Vote: yeas 11, nays 0.

